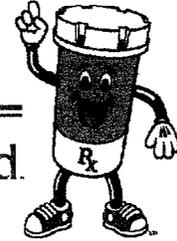


MedivoxRx

The Talking Bottle People

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A division of **wizzard.**

June 14, 2004

Division of Dockets Management [HFA-305]
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments to Docket No. 2004N-0221

The documents enclosed are our responses to the information requested in regard to the study on making prescription drug information accessible for blind and visually impaired individuals as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Headquartered in Rochester, New York, MedivoxRx Technologies, Inc. was founded in 1995 by Anthony R. Mariano and Randy Allnatt and incorporated in January 2002. Over nearly five years of development, Mariano and Allnatt developed and tested various technologies in their search to find an assistive aid device that would permit blind patients to independently access information on their medication bottles.

In 1998, the President's Safety Commission was tasked with finding ways to decrease the number of deaths associated with medication errors in the United States. The MedivoxRx Disposable Talking Bottle meets the new "standard of care" specifications of the President's Safety Commission.

With the development of the "Rex" Disposable Talking Bottle, MedivoxRx has met its original goal: To manufacture a disposable talking bottle that provides audible label information and thus makes information about their medications more accessible to people who are visually and cognitively impaired, illiterate, or speak a different language. After testing several prototypes, the "Rex" Disposable Talking Bottle was the overwhelming choice. Multiple patents are currently pending in the U.S. and several other countries.

In addition to our response, more detailed information may be found at our website located at www.rxtalks.com. MedivoxRx Technologies, Inc. was recently acquired by Wizzard Software Corp. As a result, the "Rex" Disposable Talking Bottle is entering its next generation and a product with expanded features will be available shortly.

I will of course be happy to address any questions that you might have.

Sincerely,

Eugene J. Franz
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wizzard

We make technology listen to you.™

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2004N-0221

C3

REX

FEATURES & BENEFITS



BENEFITS

- * No usage training for patient
- * Works in the freezer and damp climates
- * Disposable - no cross contamination concerns
- * Inexpensive to provide to patients

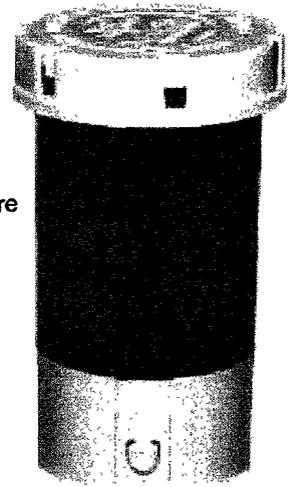
MedivoxRx

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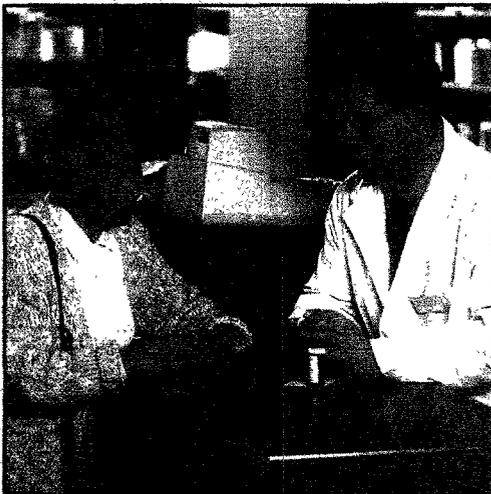


FEATURES

- * Easy to use - one push button
- * Requires no special "reader"
- * Disposable - no batteries to purchase or recharge
- * No ancillary equipment necessary
- * Automated electronic transfer of information
- * Highest quality speech synthesis
- * Manual voice override feature
- * 15 languages available including Spanish
- * Requires no changes to existing pharmacy software
- * Created by VA Pharmacist and Visual Impairment Services Team (VIST) Coordinator
- * Tested with Veterans
- * In use at several VA's today



FUTURE SOLUTIONS



At MedivoxRx, we realize that a talking pill bottle is a great help to many people but it is not a complete solution to the growing compliance problems our system faces daily. That is why we are dedicated to working with our partners and customers to grow our Rex product into a more complete, overall compliance solution. Future version's of Rex, some already in the final stages of development, will include:

- * Automatic loading of audio while traditional label is being printed
- * Up to 30 different synthesized languages
- * Audio volume control for people with hearing impairments
- * Audio "time to take your medicine" reminder
- * Audio "exceeding dosage amount" warnings
- * Audio refill reminder
- * Automated telephone reminders
- * Automated telephone refill reminder
- * Automated telephone refill ordering system

- More than 90 million adults have a limited ability to read or understand instructions on prescriptions or medicine bottles. (3)
- People aged 16 or older that have low health-literacy skills consume more health-care services. (4)
- Additional health expenditures related to low health-literacy skills total about \$73 billion (in 1998 health-care dollars): the same amount that Medicare pays for physician, dental, home health, prescription drug, and nursing home services combined. (4)
- Estimated annual cost of blindness to the federal government is \$4 billion. (5)

REFERENCES:

- (1) JAMA; 1998; 279, 1200-5. IOM, November 1999
- (2) National Eye Institute
- (3) Center for Health Care Strategies, Inc. and National Academy on an Aging Society, "Low Health Literacy Increases Expenditures," U.S. Medicine, May 1999
- (4) National Academy on an Aging Society
- (5) Prevent Blindness America 1994

2. Is there an appropriate way to divide this population into subpopulations to better evaluate needs and beneficial technologies?

RESPONSE:

Age and Type of Impairment that causes blindness or the inability to read printed prescription information are two categories.

Younger people are more receptive to "high tech" solutions and older people need simplified solutions

Some impairments have secondary problems – diabetes, and neuropathy that may create additional challenges or barriers.

B: Information About the Use of Prescription Medication Information By people Who Are Blind or Visually-Impaired:

1. How do people who are blind and visually-impaired currently get their prescription drug information?

RESPONSE:

They get the information in print form like anyone else which requires them to seek verbal explanation or interpretation. This assistance is from a pharmacist, visiting nurse, family member or significant other. (Note: this is different from identification – identifying drugs does not imply knowledge of instruction, cautions or complications on the therapy).

2. What aspects of visual impairment are important to addressing the issue of access to prescription drug information? What other factors (see examples listed in Question #A1) might be important to addressing this issue?

RESPONSE:

The extent of loss as in visual acuity is important. This ranges from total loss of light perception to "legal blindness" to low vision. The greater the degree of loss is, the greater the difficulty in accessing that prescription information.

A large part of the visually impaired population is elderly. They may suffer from cognitive impairment and physical impairment that further diminishes their ability to access and understand prescription drug information. Complex assistive devices have limited benefit in these situations.

Socioeconomic status is another factor. Inadequate financial resources affect the ability to afford the assistive technology and/or the training needed to utilize it.

Literacy is another factor. The inability to read at all or possessing only limited English language skills further complicates impaired vision.

3) How can essential drug information be effectively communicated to people who are blind and/or visually impaired?

RESPONSE:

Essential information can be effectively communicated by providing, at a minimum, verbal patient therapy information to the patient. Access to this verbal information must be provided whenever and wherever they need it, and not just from the pharmacist or family member. Access must be simple and convenient.

Discussion/definitions

Permanently affixed: It is vital that this verbal information by way of an assistive device is recorded and permanently affixed to the prescription vial and that pharmacists/or authorized allied healthcare providers have the control on the final issuance of this information. This is to assure that correct therapy and drug information instructions are dispensed to the patient and comply with various state and federal laws that govern the dispensing of both drugs and therapy information to patients.

Accessibility: Implies the **affordability** and the **direct access** to verbal instructions permanently affixed to the prescription vial. The information is to be permanently affixed to the vial along with playback of these instructions without the additional higher cost for ancillary equipment or training for its use. Training for products that require scanners or readers may not be accessible or affordable in certain healthcare settings. Pharmacy Mail Order companies would not be able to provide the necessary hands on training needed for many patients who require

it. Additionally, language barriers for many non-English speaking immigrants or citizens who are visually impaired or blind would not benefit from audio instructions in English only. Although Braille can be an effective method for some for information access, relatively few blind and/or visually impaired people can read Braille. Neuropathy complicates or prevents the use of Braille.

4. Are there data associating medication errors with blindness? With visual impairment? What types of medication errors are most common among people who are blind or visually impaired?

RESPONSE:

Most data found in research is based on medication errors due to illiteracy. Data on medication errors due to blindness does not appear to be collected in this manner. However, illiteracy is the only one identified, and if this is the inability to visually read the instructions and/or to be able to understand and comply to their individual therapy plan effectively, then visual impairments could very well figure into those data.

Note: It should be noted that individuals who are visually impaired cannot read print. By the nature of their impairment, the research studies and data that address medication errors with illiteracy may have significant association.

C. Information About Existing and Emerging Technologies (Including Internet based Information Sources):

1) What assistive technologies are currently used by people who are blind or visually impaired? In what setting?

RESPONSE:

The technologies being used may be categorized into two groups: High Tech and Low-Tech solutions. All types of technology are present for "in-home" use. Consumers who are receiving services through state or federal vocational rehab agencies primarily find High Tech solutions in use. Low Tech solutions have lower acquisition and start up costs and are simple to use. Low Tech is found in both the public and home settings.

Low-Tech solutions are further subdivided into two categories that simply identify the medication, and / or dose schedule.

The first category includes such devices as the pill trays, raised dots, colored pill caps, time & date reminders caps and rubber bands.

The second group for low-tech solutions includes those devices that provide full access to prescription information (such as hand held magnifiers and simple audio playback products, i.e. talking bottles.)

High tech solutions provide full access but in a more complicated manner (requiring ancillary equipment and/or maintenance cost. for equipment use. Closed Circuit Television (CCTV), automated pill dispensing systems, and prescription scanning devices are examples. High tech solutions have additional training expense associated with them.

2) What proportion of people who are blind currently use these technologies?

RESPONSE: We do not know of a specific proportion, but the low-tech solutions are the most widely used because of economic accessibility.

Are there specific characteristics (see examples listed in Question #A1) of this “user” population that distinguish them from blind and visually-impaired individuals who do not use these technologies?

RESPONSE:

Economic characteristics stand out again. The CCTV high tech solution, for instance, remains high cost and its use is restricted. It is not feasible for many to pay out of pocket for this type of technology. Distribution and access is very limited and restricted. Usually, access to such technologies is provided through federal or state programs.

And once again, age is a factor. The cognitive and physical difficulties that come with age can limit the individuals understanding of how to use an assistive device or their ability to manipulate / use a complex device.

3) Are there data on the effectiveness of these technologies?

RESPONSE:

No, or at least none of which we have an awareness. However, the Social Security Administration recognizes the CCTV as a “necessary medical device” when prescribed by a physician. Such technology is necessary for patients who require access to medical information.

Although, no long-term studies on such technology have been available, the Social Security Administration has recognized the need for this type technology for many years. They do provide for issuance of the high-tech products that include high cost close circuit TVs which may be used for access of printed medical /prescription information. Furthermore, the United States Department of Veterans Affairs has recently issued a directive 304, mandating the local VA hospitals to provide audio access to prescriptive information to the blinded veterans.

4. Do these technologies contribute to an increase or decrease in medication errors reported among people who are blind or visually impaired?

RESPONSE:

There are personal testimonies reported in the news media that highlight errors without the use of technology. Reporting of the errors and the consequences are more prevalent than the success stories. See item regarding Randy Allnatt at www.rxtalks.com.

5) What is the cost of these technologies?

RESPONSE:

Reading and scanning systems can range from \$700 to \$5,000. That range covers full access equipment to read or have the print read. Audible prescription products have recently come onto the market and the range of cost is hard to express for the following reasons. There is a cost to the provider (pharmacist, hospital, etc.) and a cost to the patient or end user. Depending on the support of various federally based agencies, healthcare providers, and insurers, the cost to the patient can be affordable and even nominal (\$1 to \$3 per prescription).

6) Who are the primary purchasers of these technologies?

RESPONSE:

State Vocational Rehabilitation Agencies, Associations for the Blind, and Governmental Agencies are the primary purchasers of these products in behalf of their patients / clients. Individuals in the lower income ranges or with poor economic status would likely be unable to afford these products without financial assistance. They would more than likely purchase low technology solutions. The high technology solutions are issued under federal or state programs for eligible beneficiaries

Is use of these technologies currently subsidized by any government or private program?

RESPONSE:

Yes. Social Security/Medicare, and the United States Department of Veterans Affairs subsidizes these types of programs.

7) What are barriers to use of these assistive technologies?

RESPONSE:

The largest barrier to patients to for accessing this type of technology is the prohibitive cost of the product itself, and for certain technologies, the additional cost necessary for training the patient to use scanners and reader systems.

Pharmacies report that patients who are already burdened with higher co-pays or with little or no insurance coverage are unable to afford the additional cost of the assistive devices. Pharmacies themselves report they cannot afford to provide the cost of "their time" without compensation in training patients to use specific talking devices that require scanners and readers systems.

8) What is the practicability of these assistive technologies?

RESPONSE:

Talking bottles are very practical, one hundred percent accurate, and one push button easy to use. Patients who have difficulty in reading comprehension and/or inability to read print will have greater access to individualized therapy instructions via audio/verbal instructions any time they require it.

9) How do people who are blind or visually impaired learn of these technologies?

RESPONSE:

Federal, State and Local agencies for the blind are the primary sources of information. Additionally, there are public service programs and announcements, and finally advertising, which due to its cost is generally limited to service providers. High technology solutions are so costly and usually publicly funded (federal/state programs) that they are not marketed directed to the consumer.

9a) What are the most effective resources for conveying information about these assistive technologies to blind and visually impaired individuals?

RESPONSE:

Audio – Radio Reading Services, Radio Public Service Announcements (TV also), and the usual channel of Federal, State and Local agencies serving people with disabilities. Medical service providers are another source for reaching out to those patients that require assistance.

The best direct method is having the physicians and the allied health providers be the ones to determine the need for the technology for their patient and be able at the time of the visit, write a prescription for talking pharmacy bottles/vials. The process would be similar to receiving diabetic supplies via prescription.

Accountability for purchase and need is associated with the written Rx. This remains consistent as a pharmacy function and a service to the patient. Reimbursement for rendering such services to the pharmacy would take place through the customary billing procedures.

Other sources: Conveying information on such products can be through Human Service providers such as: The National Federation of the Blind, American Counsel of the Blind, American Foundation for the Blind, Blinded Veterans Association, etc.

10) Are there emerging technologies that show promise? If so what is the anticipated cost and time?

RESPONSE:

The "Rex" talking bottle developed and manufactured by MedivoxRx Technologies Inc., a division of Wizard Software Corp. is the only disposable, one push button, and easy to use talking prescription vial/bottle on the market today.

"Rex" talking bottles are totally self-contained, portable, low cost, and disposable.

"Rex" is at home in two different environments:

- Pharmacy or other medication dispensing facility
 - "Rex" can communicate with and interface to existing pharmacy systems with a simple "handshake".
 - When the pharmacist or technician prepares a label for the prescription bottle, MedivoxRx captures that information, converts the text to speech and records it onto the "Rex" bottle.
- Home Use
 - Medication instructions can be recorded through the use of a small recording unit containing a microphone. The instructions are spoken into the microphone and recorded onto the "Rex" bottle.
 - This technology can thus also be applied to identification of food spices and other items that can be stored in the available sizes of "Rex" bottles.

In all cases, the patient pushes a single button on the bottle and the medication instructions, warnings, and other medication label information is read to the patient. It is a simple one hand operation. Among the advantages are:

- No separate player, scanning devices or ancillary equipment are required.
- No additional training is needed to use this bottle.
- It has an ergonomic ridge that guides the visually impaired and blind patient to the activating button.
- The bottle and its contents may be refrigerated as required.
- In addition to being an assistive device for the blind or visually impaired, it is a valuable tool for the cognitively impaired, physically impaired or the illiterate patient.
- Since it is totally self contained, it "travels" easily.
- It will include up to 19 different languages including Spanish in 3 dialects.

The product is currently in use in a number of United States Department of Veterans Affairs facilities, some state agencies and by end users. It will be more widely available in a newer version in the next 90 days.